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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/549,864

05/23/2006

Michael J. Lee

52000/A599

7190

23363 7590 12/28/2007
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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/549,864 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | Brandon Jackson | 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The abstract of the disclosure is objected to because it is not on a separate sheet apart from any other text. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 26-27, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Trademarks may not be claimed, the generic terminology must be used instead.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 15-16, 18-21, 25-26, 28-34 are rejected under 35

U.S.C. 102(b) as being anticipated by Marx (US Patent 4,790,300). Marx discloses a dynamic supinated splint (10) comprising a splint body (fig. 1) comprising an axis having first strap (61) for fixing a part of an arm to the splint body (fig. 1), a second strap (61) for fixing a second part of the arm to the splint body (fig. 1), a first anchor and second anchors (51, aperture in 22), and an outrigger (11) comprising two generally vertical section (14, 15) and a generally horizontal section (16) disposed between the first and second anchors (51, aperture in 22) having the outrigger (11) secured to the body such that it transects the splint body (fig. 1). A force generator (17, 42) is engaged to the first and second anchors (51, aperture in 22) at its two ends and expanded at a point between the two ends by the horizontal section (16) of the outrigger (11) to provide torque to the splint body (fig. 1). The length of the horizontal section (16) of the outrigger (11) is shorter than the length of the vertical section (14, 15) because the distance from below the wrist to the about the knuckles is longer than the distance across the back of the hand. The end of each vertical section (14, 15) is formed from bending a portion (fig. 4) of the vertical sections (14, 15). The splint body (fig. 1) comprises a proximal section (21) comprising a curved section extending laterally (57) the axis of the splint body (fig. 1). The curved section terminated just distal of a lateral epicondyle and partially covers at least a portion of a radius and ulna of a forearm when the splint is worn. The second strap (61) connects the curved section with the axis portion of the splint body (fig. 1). The two straps (61) comprise hook and loop material (col. 5, lines 50-52). The distal hand support section (22) comprises two folded

flaps (col. 6, lines 3-8) configured to a portion of the first and fifth metacarpal. The hand support section (22) comprises a bend. The splint body (fig. 1) is made from Marx discloses the splint material is any suitable splinting or casting materials, such as a low temperature thermoplastic material (col. 5, lines 37-42), which inherently includes a polycaprolactone base. The force generator (17, 42) is inherently tied/secured to the first and second anchors (51, aperture in 22). Each base of sections (12, 22) is bent and attached by splint material. The splint materials (col. 5, lines 37-42) is pliable. The proximal anchor (51) is made of splint material in a V-shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 9, 11, 17, 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marx (US Patent 4,790,300). Marx substantially discloses the

claimed invention; see rejections to claims 1, 4-6, and 33 above. Marx fails to disclose a third strap with hook and loop material disposed between the first and second straps, an opening in the hand support, the splint body is 1/8 inch thick, and the second anchor being bent/V-shaped splint material. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Marx device to have a third strap with hook and loop material disposed between the first and second straps, since it has been held that mere duplications of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With respect to claims 17 and 27, it would have been an obvious matter of design choice to have the splint body (fig. 1) made from a 1/8 inch thick sheet of splint material, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

With respect to claim 11, the opening in the hand support provides no advantage, is not used for a particular purpose, and does not solve a stated problem. The Marx device would function equally as well with an opening in the support. Therefore, it is a mere design choice and would be obvious to one of ordinary skill in the art at the time of the invention to modify the Marx hand support to have an opening.

With respect to claim 36, since the first anchor (51) is a piece of bent/V-shaped splint material, it would have been obvious to use the same configuration as the anchor on the hand support (22) instead of the apertures because they are functionally

equivalent and would allow easier removal of the hand support (22) when the splint (10) is to be removed.

Claims 12-14, 22-24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US Patent 4,790,300) in view of Hopkins et al. (US Patent 6,357,237). Marx substantially discloses the claimed invention; see rejections to claims 1, 20, and 33 above. Marx fails to disclose the force generator is made of a rubber tube. However, Hopkins teaches an orthotic device (10) comprising a force generator (30) made of a rubber tube (col. 3, lines 48-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the Marx force generator for the force generator, as taught by Hopkins, because it is a resilient material that can be reused often and is also a well known material in the art used for force generators.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sieller et al. (US Patent 7,156,819) Bonutti (US Patents 5,685,830; 5,456,268; 5,213,094; 5,167,612; 5,365,947), Gyovai et al. (US Patent 4,949,711).



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  12/20/07
Brandon Jackson
Examiner
Art Unit 3772

BLJ


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12/21/07